UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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UNITED STATES OF AMERICA, ALASKA, CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, VIRGINIA, WASHINGTON, AND THE DISTRICT OF COLUMBIA, *ex rel.* MARY BIXLER WOOD,

Plaintiffs,

v.

SIEMENS MEDICAL SOLUTIONS USA, INC., SIEMENS HEALTHCARE DIAGNOSTICS, INC., AND SIEMENS HEALTHCARE DIAGNOSTICS PRODUCTS GMBH,

Defendants.

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**ORDER**
21-CV-1947 (MKB)

MARGO K. BRODIE, United States District Judge:

Plaintiff-Relator Mary Bixler Wood ("Relator"), acting on behalf of the United States of America, thirty states, and the District of Columbia, commenced the above-captioned action on April 12, 2021, against Defendants Siemens Medical Solutions USA, Inc., Siemens Healthcare Diagnostics, Inc., and Siemens Healthcare Diagnostics Products GmbH (collectively, "Defendants"). (Compl., Docket Entry No. 1.) Relator alleged Defendants violated provisions of the False Claims Act, 31 U.S.C. § 3729 *et seq.* ("FCA") barring the presentation of false claims, the use of false statements, and conspiracies to violate the FCA as well as various state law FCA analogs. (Am. Compl., Docket Entry No. 8; Second Am. Compl. ("SAC"), Docket

Entry No. 43.)[1] On March 12, 2024, Defendants moved to dismiss the SAC pursuant to Rules 9(b) and 12(b)(6) of the Federal Rules of Civil Procedure. (Defs.' Mot. to Dismiss the SAC ("Defs.' Mot."), Docket Entry No. 51.) On January 17, 2025, the Court granted Defendants' motion to dismiss (the "January 2025 Decision"). (Jan. 2025 Decision, Docket Entry No. 58.)

On January 29, 2025, Relator filed a motion for reconsideration of the Court's January 2025 Decision. (Pl.'s Mot. for Recons. ("Pl.'s Mot."), Docket Entry No. 59; Pl.'s Mem. in Supp. of Pl.'s Mot. ("Pl.'s Mem."), Docket Entry No. 59-1.) For the reasons discussed below, the Court denies the motion.

## I. Background

The Court assumes familiarity with the facts as detailed in the January 2025 Decision, and therefore provides only a summary of the pertinent facts.

Relator argues that "for many years, Siemens has knowingly shipped temperature-sensitive [in vitro diagnostics ("IVDs")] well outside their FDA-approved or -cleared temperature ranges." (SAC ¶ 112.) According to Relator, Defendants "ha[ve] not conducted stability testing to validate the accuracy of the information on its device labels" and "knows that the expiration and shelf life information on its devices is inaccurate." (*Id.* ¶ 115.) "[T]o the extent Siemens conducted stability testing," such testing "demonstrated that certain devices either fail or are not safe and effective within the shelf life stated on the device labels." (*Id.*) "Siemens was aware since at least 2009 that the shippers used by the company to transport IVDs

[1] On August 31, 2022, Defendants moved to dismiss the Amended Complaint pursuant to Rules 9(b) and 12(b)(6) of the Federal Rules of Civil Procedure. (Defs.' Mot. to Dismiss, Docket Entry No. 25.) The Court dismissed the Amended Complaint and granted Relator leave to file a second amended complaint. (Sept. 2023 Decision, Docket Entry No. 34.) On November 17, 2023, Relator filed the SAC, omitting Siemens Healthcare Diagnostics Products GmbH as a Defendant, but alleging identical claims against Siemens Medical Solutions USA, Inc. and Siemens Healthcare Diagnostics, Inc. (SAC ¶¶ 10–12.)

to customers resulted in exposure of IVDs to temperatures well outside of their FDA-approved frozen or refrigerated ranges, rendering the shipped devices both adulterated and misbranded, with no assurances or reliability, safety or efficacy." (*Id.* ¶ 141.)

Relator contends that Siemens caused others to submit false claims, which "did not disclose . . . the compromised reliability, safety and efficacy of the IVDs resulting from Siemens' non-compliance with FDA medical device laws and regulations," to Federal Health Care Programs for the use of its compromised IVD products. (*Id.* ¶ 189.) "Siemens also sold those compromised IVD products directly to the Government." (*Id.* ¶ 190.)

In the January 2025 Decision, the Court dismissed Relator's claims for failure to satisfy the particularity requirement of Rule 9(b) of the Federal Rules of Civil Procedure. (Jan. 2025 Decision 14.) The Court concluded that Relator's allegations "only indicate that the IVDs malfunctioned" without making specific allegations that the IVDs malfunctioned as a result of Defendants' improper storage or shipping practices. (*Id.* at 14–15.) The Court also found that Relator failed to state a FCA claim because of her failure to allege that Defendants' shipping practices compromised IVDs for which claims to the government were actually submitted. (*Id.* at 15.) Because the Court concluded that Relator failed to allege an independent FCA claim, the Court dismissed her FCA conspiracy claim and declined to exercise supplemental jurisdiction over her state law claims. (*Id.* at 16–17.)

## II. Discussion

### a. Standard of review

The standard for granting a motion for reconsideration "is strict, and reconsideration will generally be denied unless the moving party can point to controlling decisions or data that the court overlooked — matters, in other words, that might reasonably be expected to alter the

conclusion reached by the court." *Commerzbank AG v. U.S. Bank, N.A.*, 100 F.4th 362, 377 (2d Cir. 2024) (quoting *Shrader v. CSX Transp., Inc.*, 70 F.3d 255, 257 (2d Cir. 1995)); *Van Buskirk v. United Grp. of Cos., Inc.*, 935 F.3d 49, 54 (2d Cir. 2019) (same); *see also* S.D.N.Y. & E.D.N.Y. Local Civ. R. 6.3 (providing that the moving party must "set[] forth concisely the matters or controlling decisions which counsel believes the [c]ourt has overlooked"). "Controlling decisions include decisions from the United States Court of Appeals for the Second Circuit; they do not include decisions from other circuits or district courts . . . ." *Pentacon BV v. Vanderhaegen*, No. 23-CV-2172, 2024 WL 3835334, at *12 (S.D.N.Y. Aug. 15, 2024) (quoting *Cobalt Multifamily Invs. I, LLC v. Shapiro*, No. 06-CV-6468, 2009 WL 4408207, at *2 (S.D.N.Y. Dec. 1, 2009)); *see also Tenemille v. Town of Ramapo*, No. 18-CV-724, 2022 WL 2047819, at *5 (S.D.N.Y. June 7, 2022) (quoting same). In addition to considering any evidence or controlling cases the court overlooked, the court should also consider whether there has been "an intervening change of controlling law." *Commerzbank AG*, 100 F.4th at 377 (quoting *Virgin Atl. Airways, Ltd. v. Nat'l Mediation Bd.*, 956 F.2d 1245, 1255 (2d Cir. 1992); *Ethridge v. Bell*, 49 F.4th 674, 688 (2d Cir. 2022) (quoting *Kolel Beth Yechiel Mechil of Tartikov, Inc. v. YLL Irrevocable Tr.*, 729 F.3d 99, 104 (2d Cir. 2013)); *Johnson v. Mount Sinai Hosp. Grp., Inc.*, No. 22-CV-2936, 2023 WL 3159233, at *1 (E.D.N.Y. Apr. 28, 2023) (quoting same).

It is thus well-settled that a motion for reconsideration "is not a vehicle for relitigating old issues, presenting the case under new theories, securing a rehearing on the merits, or otherwise taking [another] bite at the apple." *U.S. for Use & Benefit of Five Star Elec. Corp. v. Liberty Mut. Ins. Co.*, 758 F. App'x 97, 101 (2d Cir. 2018) (alteration in original) (quoting *Analytical Survs., Inc. v. Tonga Partners, L.P.*, 684 F.3d 36, 52 (2d Cir. 2012), *as amended*, (July 13, 2012)). "A motion for reconsideration is not an opportunity for a [party] to 'relitigate

an issue already decided' or present arguments that could have been made before the judgment was entered." *Ethridge*, 49 F.4th at 688 (quoting *Shrader*, 70 F.3d at 257); *see also Doe v. Martucci*, No. 20-CV-2331, 2024 WL 5118505, at *2 (S.D.N.Y. Dec. 16, 2024) ("[A] motion for reconsideration is neither an occasion for repeating old arguments previously rejected nor an opportunity for making new arguments that could have been previously advanced." (quoting *Assoc. Press v. U.S. Dep't of Def.*, 395 F. Supp. 2d 17, 19 (S.D.N.Y. 2005); *Salveson v. JP Morgan Chase & Co.*, 166 F. Supp. 3d 242, 248 (E.D.N.Y. 2016) ("A motion for reconsideration is 'neither an occasion for repeating old arguments previously rejected nor an opportunity for making new arguments that could have previously been made.'" (quoting *Simon v. Smith & Nephew, Inc.*, 18 F. Supp. 3d 423, 425 (S.D.N.Y. 2014))), *aff'd*, 663 F. App'x 71 (2d Cir. 2016).

**b. Relator has not stated a valid basis for reconsideration**

In support of her motion for reconsideration, Relator argues that the Court's January 2025 Decision "overlooked a critical distinction for FCA liability purposes between Relator's contract-based FCA claims and her insurance-based FCA claims." (Pl.'s Mem. 1.) Relator argues that the Court "overlooked the fact that whether Relator can demonstrate that [specific] IVDs malfunctioned as a result of temperature noncompliance or connect such malfunction to a submitted claim is entirely irrelevant to Relator's contract-based FCA claims." (*Id.*) Relator contends that the contract-based FCA claims, unlike the insurance-based claims, "are not predicated on whether Siemens IVDs are reimbursable as medically necessary under any Federal Health Care Program or functioned as intended" [2] but are based on (1) "the statutory provision

[2] The Court recognizes that Relator "does not concede that the Court's ruling on her insurance-based FCA claims is correct" and "reserves all her procedural rights concerning the insurance-based FCA claims alleged in the SAC." (Pl.'s Mem. 3 n.2.) Relator argues her "insurance-based FCA claims . . . arise under Federal Health Care Program requirements

found at 21 U.S.C. § 331(c) prohibiting 'the delivery or proffered deliver[y] thereof for pay or otherwise' of any misbranded or adulterated device" and (2) "the material conditions within government contracts mandating compliance with FDA regulations and other requirements governing medical devices." (*Id.*) Relator further argues that these claims "depend only on whether Siemens violated the criminal law (21 U.S.C. § 331(c)) and government contracts by knowingly selling" adulterated IVDs "without disclosing their noncompliant condition" to the government, regardless of whether the IVDs still "functioned correctly" after the allegedly improper shipment. (*Id.* at 2.) Relator argues that she has "specifically alleged that these statutory, regulatory and contract requirements were material to payment and that Siemens' failure to comply and disclose its noncompliance to the government rendered Siemens' contract claims false within the meaning of the FCA under both express and implied contract obligations." (*Id.* at 4.) Accordingly, Relator argues that she satisfied Rule 9(b) by alleging that (1) "Siemens IVDs were adulterated and misbranded for failure to comply with FDA regulations requiring temperature compliance during shipping"; (2) "Siemens was contractually and legally obligated to sell only FDA-compliant IVDs that were *not* adulterated or misbranded"; and (3) "the government purchased Siemens IVDs during the period that Relator alleges such IVDs were adulterated and misbranded due to Siemens' noncompliant shipping practices." (*Id.* at 9.)

The Court denies Relator's motion for reconsideration because her arguments about her "contract-based FCA claims" do not alter the Court's conclusion that Relator has failed to sufficiently allege an FCA violation. (*Id.*) Even assuming, as Relator argues, that the IVDs Siemens shipped outside of the temperature range would amount to "adulteration" of the IVDs,

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expressly linking the reimbursement eligibility of Siemens IVDs to their medical necessity." (*Id.* at 2.) However, Relator does not argue that the Court overlooked evidence or controlling decisions with regard to Relator's "insurance-based claims."

(*id.*), it is not clear that "adulteration, without more, renders a claim legally false" and courts that "have had the opportunity to consider whether [Federal Food, Drug, and Cosmetic Act ("FDCA")] violations are specifically actionable under the FCA have held that they are not." *United States ex rel. Powell v. Medtronic, Inc.*, No. 18-CV-1628, 2024 WL 4165522, at *13 (S.D.N.Y. Sept. 12, 2024); *see also United States ex rel. Yu v. Grifols USA, LLC*, No. 17-CV-2226, 2021 WL 5827047, at *8 (S.D.N.Y. Dec. 8, 2021) (holding that a device was not "adulterated" under the FDCA because failing to comply with "regulatory guidance and program manuals that emphasize that drugs reimbursed for or purchased by" the government "should be safe and not adulterated" are merely "[g]eneric and routine appeals to the importance of . . . broad goals."), *aff'd*, 2022 WL 778504 (2d Cir. Oct. 14, 2022).

Relator's argument that Defendants violated "material" terms of their government contracts also fails. Relator has not shown that shipping the IVDs outside of the FDA-approved temperature range constitutes "adulteration" or renders the IVDs ineffective, and there is therefore no support for Relator's claim that Siemens violated an "assumed and material element" of government contracts by delivering IVDs that are not "reliable, safe and effective" or were "misbranded or adulterated at the time of delivery." (SAC ¶ 76.) The Court addressed this argument in the January 2025 Decision, concluding that Relator "fail[ed] to specifically allege" that shipping the IVDs outside of their FDA-approved temperature range actually caused them to malfunction." (Jan. 2025 Decision 14–15.) In addition, even assuming Defendants' shipping practices violated statutory and contractual requirements, Relator has only made conclusory allegations that compliance with such requirements is "material." (SAC ¶ 76.) The Supreme Court has held that a "misrepresentation cannot be deemed material merely because the Government designates compliance with a particular statutory, regulatory, or contractual

requirement as a condition of payment." *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 194 (2016); *see also Conte v. Kington NH Operations LLC*, 585 F. Supp. 3d 218, 240 (N.D.N.Y. 2022) ("In other words, materiality is not assumed merely because a defendant misrepresented its compliance with a statutory, regulatory, or contractual obligation" (citing *Universal Health*, 579 U.S. at 191)).

Relator's arguments that shipping IVDs outside of the FDA-approved temperature range, without evidence that doing so actually caused any IVDs to malfunction, and without allegations that those IVDs were paid for by the Government, is insufficient to support even her contract-based FCA claim.

## III. Conclusion

For the reasons stated above, the Court denies Relator's motion for reconsideration. The Court grants Relator an extension of time to file a third amended complaint. Any third amended complaint must be filed within thirty days from the filing of this Order. If a third amended complaint is not timely filed, the Court will direct the Clerk of Court to enter judgment and close this case.

Dated: February 12, 2025
Brooklyn, New York

SO ORDERED:

s/ MKB
MARGO K. BRODIE
United States District Judge